a final draft of the guidance was submitted to the ICH Assembly and endorsed by the regulatory agencies on June 16, 2016.

Regulatory authorities approve drugs that are demonstrated to be safe and effective for human use. The meaning of “safe” has historically been interpreted to mean that the benefits of the drug outweigh its risks. This benefit-risk assessment of pharmaceuticals is the fundamental basis of regulatory decision-making. In the last several years, providing greater structure for the benefit-risk assessment has been an important topic in drug regulation. The M4E guidance directs applicants to include their conclusions on benefits and risks in the Clinical Overview of Module 2 of the Common Technical Document (CTD) under section 2.5.6. Although general guidance is provided in the M4E guidance regarding the expected content of section 2.5.6, no further structure is suggested to aid industry in developing the benefit-risk assessment. As a result, regulators observe a high degree of variability in the approaches taken by applicants in presenting this information. This variability may not facilitate efficient communication of industry views to regulators. Although regulators and industry have developed approaches for structured benefit-risk assessment and these approaches may take different forms, there is a common thread evident that can inform harmonization of the format and structure of benefit-risk assessments provided by applicants in their regulatory submissions.

The revised M4E(R2) guidance provides more specific guidance regarding the format and structure of the benefit-risk assessment in section 2.5.6. Section 2.5.6 is divided into four subsections: (1) Therapeutic context, (2) Benefit, (3) Risk, and (4) Benefit-Risk Assessment. Each subsection describes the aspects that are most pertinent to the benefit-risk assessment. This guidance also lists characteristics that should be considered when identifying and describing key benefits and key risks of the medicinal product. Recognizing that there are many reasonable approaches for conducting a benefit-risk assessment, M4E(R2) does not specify a particular approach to be used by industry. However, the document does offer specific guidance on the major elements that should be included in the benefit-risk assessment. Furthermore, the revised guidance does not dictate an approach used by a regulator in conducting a benefit-risk assessment. This guidance also revises other sections of the guidance for clarification, given the proposed revisions in section 2.5.6. In addition, the revised guidance changes the numbering and the section headings for consistency.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at https://www.regulations.gov, http://www.fda.gov/Drugs/Guidance, Part D,
Dockets Management Staff (DAB3)
Office of the Chief Scientist (DAE)
National Center for Toxicological Research (DAEC)
Office of the Center Director (DAECA)
Office of Management (DAE CB)
Planning and Resource Management Staff (DAE CB A)
Office of Research (DAE CC)
Division of Biochemical Toxicology (DAE CC A)
Division of Genetic and Molecular Toxicology (DAE CC B)
Genetic Toxicology Lab (DAE CC B 1)
Division of Microbiology (DAE CC D)
Division of Systems Biology (DAE CC E)
Division of Neurotoxicology (DAE CC F)
Division of Bioinformatics and Biostatistics (DAECC H)
Office of Scientific Coordination (DAEC F)
Office of Counter-Terrorism and Emerging Threats (DAEG)
Office of Scientific Integrity (DAEI H)
Office of Regulatory Science and Innovation (DAEI L)
Division of Science Innovation and Critical Path (DAE IA)
Division of Scientific Computing and Medical Information (DA EIB)
Office of Scientific Professional Development (DAEI)
Office of Health Informatics (DAEK)
Office of the Counselor to the Commissioner (DAR)
Office of Women’s Health (DAS)
Office of External Affairs (DAU)
Web and Digital Media Staff (DAU 1)
Administrative Management Staff (DAU 2)
Office of Media Affairs (DAUA)
Web Communications Staff (DAUA 2)
Office of Communications (DAUB)
Communications Staff (DAUB 1)
FDA History Office (DAUB 2)
Office of Health and Constituent Affairs (DAUC)
Office of Minority Health (DAY)
Office of Laboratory Science and Safety (DAZ)
Employee Safety and Environmental Management Staff (DAZ 1)
The Food and Drug Administration, Office of Operations (OO), has been restructured as follows:

**DMM. ORGANIZATION.** The Office of Operations is headed by the Deputy Commissioner for Operations and Chief Operating Officer and includes the following organizational units:

- Office of Operations (DMM)
- Office of Business Services (DMM 1)
- Business Operations Staff (DMM 1 1)
- Employee Resource and Information Center (DMM A 1)
- Division of Ethics and Integrity (DMM 3)
- Ombudsman and Conflict Prevention and Resolutions Staff (DMM 4)
- Office of Equal Employment Opportunity (DMM A)
- Compliance Staff (DMM A 1)
- Diversity Staff (DMM A 3)
- Office of Finance, Budget and Acquisitions (DMM D)
- Office of Budget (DMM DA)
- Division of Budget Formulation (DMM DA A)
- Division of Budget Execution and Control (DMM DB A)
- Office of Acquisition and Grant Services (DMM DB 1)
- Division of Acquisition Operations (DMM DB A)
- Service Contract Branch (DMM DB A 1)
- Contract Operations Branch (DMM DB A 2)
- Division of Acquisition Programs (DMM DB B)
- Scientific Support Branch (DMM DB B 1)
- Field Operations Branch (DMM DB B 2)
- Facilities Support Branch (DMM DB B 3)
- Division of Regulatory Inspections Acquisitions and Grants and Assistance Management (DMM DB C)
- Grants Management Branch (DMM DB C 1)
- Regulatory Inspections and Acquisitions Branch (DMM DB C 2)
- Division of Information Technology Acquisitions (DMM DB D)
- Information Technology Acquisitions Branch (DMM DB D 1)
- Systems Technology Acquisitions Branch (DMM DB D 2)
- Division of Policy, Systems, and Program Support (DMM DB E)
- Office of Financial Operations and Policy (DMM DC)
- Office of Financial Management (DMM DC A)
- Internal Controls, Compliance and Oversight Staff (DMM DC A 1)
- Business Transformation, Administration and Management Staff (DMM DC A 2)
- User Fee Staff (DMM DC A 3)
- Financial Systems Support Staff (DMM DC A 4)
- Division of Accounting (DMM DC A B)
- Division of Travel Services (DMM DC A C)
- Division of Payment Services (DMM DC A D)
- Office of Human Resources (DMM E)
- Commissioned Corps Affairs Staff (DMM E 6)
- Management Analysis Services Staff (DMM E 7)
- Business Operations Staff (DMM E 8)
- Division of Workforce Relations (DMM EB)
- Employee and Labor Relations Branch I (DMM EB 1)
- Employee and Labor Relations Branch II (DMM EB 2)
- Division of Policy, Programs, and Executive Resources (DMM EC)
- Policy Branch (DMM EC 1)
- Executive Resources Branch (DMM EC 2)
- Accountability Branch (DMM EC 3)
- Division of Enterprise Support Services (DMM ED)
- Resources and Information Branch (DMM ED 1)
- Systems and Records Management Branch (DMM ED 2)
- Benefits Branch (DMM ED 3)
- FDA University (DMM EF)
- Division of Human Resource Services for Office of the Commissioner/Office of Operations (DMM EG)
- Office of the Commissioner/NCTR Customer Solutions Branch (DMM EG 1)
- Office of Operations Customer Solutions Branch (DMM EG 2)
- Division of Human Resource Services for Office of Medical Products and Tobacco (DMMEH)
- CDRH Customer Solutions Branch (DMM EH 1)
- CBER and NCTR Customer Solutions Branch (DMM EH 2)
- CDER Customer Solutions Branch (DMM EH 3)
- CTP Customer Solutions Branch (DMM EH 4)
- Division of Human Resource Services for the OFVM/OGROP (DMM EI)
- CFSAN/CVM Customer Solutions Branch (DMM EI 1)
- ORA/OIP Customer Solutions Branch (DMM EI 2)
- Office of Facilities, Engineering, and Mission Support Services (DMMF)
- Jefferson Laboratories Complex Staff (DMMF 1)
- Facilities Program Staff (DMM F 2)
- Division of Operations Management and Community Relations (DMM FA)
- Logistics and Transportation Management Branch (DMM FA 1)
- Facilities Maintenance and Operations Branch (DMM FA 2)
- Auxiliary Program Management Branch (DMM FA 3)
- Division of Planning, Engineering and Space Management (DMM FB)
- Portfolio and Space Management Branch (DMM FB 1)
- Engineering Management Branch (DMM FB 2)
- Office of Information Management and Technology (DMMH)
- Office of Information Management (DMMH A)
- Information Security Staff (DMMH A 1)
- Knowledge Management Staff (DMMH A 2)
- Enterprise Architecture and Technology Innovation Staff (DMMH A 3)
- Office of Technology and Delivery (DMMH AA)
- Delivery Management and Support Staff (DMMH AA 1)
- Divisions of Infrastructure Operations (DMMH AAA)
I. Delegations of Authority

Pursuant to further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and re-delegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further re-delegations, provided they are consistent with this reorganization.

II. Electronic Access

This reorganization is reflected in FDA’s Staff Manual Guide (SMG). Persons interested in seeing the complete Staff Manual Guide can find it on FDA’s web site at: https://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm.

Authority: 44 U.S.C. 3101.

Dated: July 17, 2017.

Thomas E. Price,
Secretary of Health and Human Services.

SUMMARY:

The Health Information Technology Advisory Committee (HITAC) shall at least reflect providers, ancillary healthcare workers, consumers, purchasers, health plans, technology vendors, researchers, relevant Federal agencies, and individuals with technical expertise on health care quality, privacy and security, and on the electronic exchange and use of health information.

Members will be selected in order to achieve a balanced representation of viewpoints, areas of experience, subject matter expertise, and representation of the health care landscape. Terms will be three (3) years from the appointment date. Members serve without pay, but will be provided per diem and travel costs for committee services.

Submit Applications: Applications should be submitted electronically through the application database on the HealthIT.gov Web site at: http://U www.healthit.gov/facas/faca-workgroup-membership-application. An application package must include: A short bio, a current resume or CV including contact information, and two letters of support.


Michelle Consolazio,
Office of Policy, Office of the National Coordinator for Health Information Technology.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Information Technology Advisory Committee; Call for Applications

AGENCY: Office of the National Coordinator for Health Information Technology, HHS.

ACTION: Call for applications.

SUMMARY: The Office of the National Coordinator for Health Information Technology (ONC) is seeking applications to the Health Information Technology Advisory Committee.

SUPPLEMENTARY INFORMATION:

Name of Committee: Health Information Technology Advisory Committee.

General Function of the Committees: The Health Information Technology Advisory Committee (HITAC) shall make recommendations to the National Coordinator on a policy framework to advance an interoperable health information technology infrastructure. The Health Information Technology Advisory Committee shall recommend to the National Coordinator a policy framework for adoption by the Secretary consistent with the strategic plan under section 3001(c)(3) for advancing the following target areas (described in more detail in the Description of Duties section): (1) Achieving a health information technology infrastructure that allows for the electronic access, exchange, and use of health information; (2) the promotion and protection of privacy and security of health information in health information technology; (3) the facilitation of secure access by an individual to such individual’s protected health information; and (4) any other target area that the HITAC identifies as an appropriate target area to be considered. Such policy framework shall seek to prioritize achieving advancements in these target areas and may incorporate policy recommendations made by the HIT Policy Committee, as in existence before the date of the enactment of the 21st Century Cures Act.

Date and Time: Applications must be received by 12:00 p.m. on Friday, August 4, 2017.

Contact Person: Michelle Consolazio, email: michelle.consolazio@hhs.gov.

Background: Section 3002 of the 21st Century Cures Act (Pub. L. 114–255) establishes the Health Information Technology Advisory Committee (referred to as the “HITAC”). Once established, the Health Information Technology Advisory Committee will be governed by the provisions of the Federal Advisory Committee Act (FACA) (Pub. L. 92–463), as amended, (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees. HHS is seeking applications for two members of the HITAC; one of whom shall be appointed to be a public health official representative. Members of the HITAC shall at least reflect providers, ancillary healthcare workers, consumers, purchasers, health plans, technology vendors, researchers, relevant Federal agencies, and individuals with technical expertise on health care quality, privacy and security, and on the electronic exchange and use of health information.

Members will be selected in order to achieve a balanced representation of viewpoints, areas of experience, subject matter expertise, and representation of the health care landscape. Terms will be three (3) years from the appointment date. Members serve without pay, but will be provided per diem and travel costs for committee services.

Submit Applications: Applications should be submitted electronically through the application database on the HealthIT.gov Web site at: http://U www.healthit.gov/facas/faca-workgroup-membership-application. An application package must include: A short bio, a current resume or CV including contact information, and two letters of support.


Michelle Consolazio,
Office of Policy, Office of the National Coordinator for Health Information Technology.

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